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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WALICKA, MALGORZATA A

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,383

Applicant(s)

VREELAND, VALERIE

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15 and 17-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The Amendment filed Jan 10, 2005 is acknowledged. Claims 1-13 were cancelled previously. Nonelected claims 28-36, as well as claim 16, have been currently canceled. Claims 14-15, and 17-27 are pending and are the subject of this Office Action.

DETAILED ACTION

1. Objections

1.1. Specification

Objection to the specification has been withdrawn, because the amendment was filed.

1.2. Claim

Objections to claim 14, 17 and 18 for formal matters are withdrawn because the claims have been corrected.

3. Rejections

3.1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claim 14 made in the Office Action of October 8, 2004 (previous Office Action), is withdrawn, because the claim has been amended.

Claims 17-24 and claim 27 are rejected as depending on the canceled claim 16.

3.2. 35 USC, section 112, first paragraph

3.2.1 Lack of written description

Claims 14-15 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as

failing to comply with the written description requirement.

The claims are directed to a polypeptide comprising vanadium haloperoxidase wherein said vanadium haloperoxidase comprises:

- 1) an amino acid sequence having at least 70% sequence identity to the sequence from residue 435-632 of SEQ ID NO:2 and having a molecular weight of no more than 40 kD or
- 2) polypeptide 1) having in position corresponding to position 455 of SEQ ID NO: 2 an Ala, in position corresponding to position 457 a Cys, and at position corresponding to position 525 a Val.

Thus, the claims are directed to a large and variable genus of polypeptides comprising vanadium haloperoxidase and a large genus of methods of their use, but the structure of the polypeptides is not sufficiently disclosed in the application. The specification teaches, Fig.3, twelve polypeptides, SEQ ID NO: 2 and its truncated forms that have the claimed activity. This, however is not sufficient to identify any polypeptide having vanadium peroxidase activity, comprising an amino acid sequence having at least 70% sequence identity to the sequence from residue 435-632 of SEQ ID NO: 2 and having a molecular weight of no more than 40 kD or a polypeptide having, in addition, in position corresponding to position 455 of SEQ ID NO: 2 an Ala, in position corresponding to position 457 a Cys, and at position corresponding to position 525 a Val. Applicants did not teach which amino acid of the 435-632 residues may be changed without changing the enzymatic activity, so that the new fragment of residues 435-632 was 70% identical to is original in SEQ ID NO: 2. Those skilled in the art

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realize that even one change of amino acid in the catalytic domain may change the protein enzymatic activity or render it inactive.

In their Remarks, page 7, first paragraph Applicants argue that functional features of claimed polypeptides "can be readily tested by one of ordinary skill in the art using well established, routinely practiced techniques as well as according to the teaching of the present specification (see, e.g., page 25, line 17-29, and page 28, line 24, to page 29, line 6)."

Applicants' argument is not persuasive. The quoted passages teach how to measure the desired enzymatic activity and not how to modify the sequence consisting of residues 435-632 of SEQ ID NO: 2 so that it had the desired activity and 70% structural identity to the original fragment consisting of residues 435-632 of SEQ ID NO:2. The disclosure does not teach what is the structure of the flanking sequences so that the polypeptide as a whole were the active enzyme. The rest of the polypeptide structure is completely unknown. The problem is in the structure and not function. Furthermore, written description requirement is not satisfied by merely providing "a result that one might achieve if one made that invention"; see *Eli Lilly*, 119 F.3d at 1568. 43 USPQ2d at 1406 as quoted in MPEP page 2100-173 paragraph (2), and that is exactly what Applicant expects from one skilled in the art.

In summary, given the lack of structural characteristics of additional representative species as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise and exact terms

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that a skilled artisan would recognize Applicants were in possession of the claimed invention when the application was filed.

3.2.2. *Scope of enablement*

Claims 14-15 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 2, its twelve truncated forms presented in Fig. 3 and the method of their use, does not reasonably provide enablement for any vanadium peroxidase polypeptide comprising amino acid sequence having at least 70% amino acid identity of a sequence from residue 435-632 of SEQ ID NO: 2 or, a polypeptide that, in addition, comprises the amino acids residues as recited in claim 15 and having molecular weight not more than 40 kDa. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to the extremely large number of polypeptides encompassed by the scope of the claims; see the above above rejection for lack of written description.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any polypeptide, and its method of use, from any natural or man-made source, wherein the polypeptide:

- (1) is a vanadium haloperoxidase,

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(2) comprises a sequence that is at least 70% identical to a sequence from residue 435 to residues 632 of SEQ ID NO: 2, and

(3) comprises, in addition, in position corresponding to position 455 of SEQ ID NO: 2 an Ala, in position corresponding to position 457 a Cys, and at position corresponding to position 525 a Val,

and wherein said the molecular weight of said polypeptide is not more than 40 kDa.

While methods of gene cloning and gene structure manipulations are well known in the relevant art, and skills of the artisans highly developed, no one is able to make polynucleotides and thus encoded polypeptides listed under (1) – (3) above, because the lack of structural characteristics of said polypeptides makes the probability of success in obtaining the claimed invention very low. The only examples provided by disclosure is the polypeptide of SEQ ID NO: 2, which is vanadium haloperoxidase of *Fucus distichus*, or its 11 truncated forms. However, the specification is silent as to how to modify the structure of disclosed polypeptides so that they had features described under (1)-(4) above and retained the desired activity.

Traversing this rejection Applicant emphasizes, on page 9, the first line, " MPEP §2164.01 states: 'the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.' In the present case, the necessary experimentation requires nothing beyond the use of routine techniques, such as modification of a polynucleotide coding sequence, recombinant expression of a

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polypeptide, and peroxidase activity assays, which is exactly what 'the art typically engages in."

Applicants's arguments have been fully considered, but are found not persuasive for following reasons. Although the techniques enumerated by Applicants are routine, the invention obtained in result of their combination is not. What Applicants expect from one skilled in the art is "a result that one might achieve if one made that invention"; see *Eli Lilly*, 119 F.3d at 1568. 43 USPQ2d at 1406 as quoted in MPEP page 2100-173 paragraph (2).

In summary, without the further guidance on the part of Applicants in regards of structure of the claimed polypeptides, experimentation left to those in the art is improperly extensive and undue.

3.2. 35 USC section 102

Claims 14 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by Vilter H. [Vanadium dependent haloperoxidases, in Sigel H. Siegel A. (eds.), *Metal ions in biological system - vanadium and its role in life*, Marcel Dekker, New York 1995, pp. 323-362].

Rejection of claim 16 is moot, because the claim has been canceled. Rejection of claim 14 is withdrawn, because the claim has been amended.

The claims are directed to a polypeptide

3.3. 35 USC section 103

Claims 20-24 were rejected under this paragraph in the previous Office Action. The 103 rejection is not made in this Office Action because claims 20-24 are incomplete (*supra*); their dependence is not known and could not be gleaned from REMARKS.

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4. Conclusion

No claim is in condition for allowance. As the examiner indicated in the previous Office Action, the claims contain allowable subject matter. Applicants disclosed a novel bromoperoxidase from the species *Fucus distichus* and its truncated form. Said truncated form of bromoperoxidase is a fragment consisting of residues 435-632 of the full-length enzyme of SEQ ID NO: 2. The bromoperoxidase of SEQ ID NO: 2 as well as its truncated form consisting of amino acids residues 441-676 are disclosed in the US Patent 6,232,457, issued to Valerie Vreeland et al. on the application 09/151,189 of which the instant application is continuation in part, as well as in the US Patent 6,656,715, issued on application 09/596,794 of which the instant application is a divisional.

The bromoperoxidase set forth by SEQ ID NO: 2 and a bromoperoxidase having the sequence residues 435-632 of SEQ ID NO: 2 are free of prior art. The latter invention is also non-obvious, because one skilled in the art who has in his hand the full length sequence of SEQ ID NO: 2 cannot predict that the truncated sequence consisting of amino acids 435-632 retains the bromoperoxidase activity.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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